

# 華新橡膠工業股份有限公司



MODERN HEALTHCARE CORP.

公司：彰化縣田中鎮中州路二段 751 號  
751 CHUNG CHOU RD., SEC. 2, TIEN CHUNG  
CHANG HWA, TAIWAN R.O.C.  
TEL : 886-4-8752115-8 ; FAX : 886-8743139

MAR 21 2007

## " 510(k) SUMMARY "

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K 063043

Submitter's Name: MODERN HEALTHCARE CORP.

No.751, Chung Chou Rd., Sec. 2, Tien Chun County, Chang-Hwa, 52045, Taiwan, R.O.C.

Date summary prepared: September 29, 2006

Device Name:

- Classification name: *Mask, Surgical*
- Classification number: *FFX, Class II*
- Regulation Number: *878.4040*
- Proprietary name: *Surgical Face Mask, Type: Tie-on, Ear-loop*
- Common name of device: *Surgical Face Mask, Disposable*
- Predicate Device: *Surgical Face Mask, K060776*
- Official Correspondent: *Dr. Jen, Ke-Min*

E-mail: [ceirs.jen@msa.hint.net](mailto:ceirs.jen@msa.hint.net) (Tel) 886-3-5208829; (Fax) 886-3-5209783

Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC

Description of the device:

*Modern Healthcare Corp. Surgical Face Mask, type: Tie-on and Ear-loop, are flat pleated 3-ply (at least) masks with an inner and outer layer (spunbonded polypropylene) that sandwich a melt blown polypropylene filter material, also with elastic loops and / or strip. The nosepiece for all Modern Healthcare Corp. Surgical Face Mask is malleable aluminum wire. All the materials used in the construction of the Modern Healthcare Corp. Surgical Face Mask are being used in currently marked devices.*

Labels/Labeling:

*This device will be marked to medical device suppliers, Dentist and Doctor Officers, clinics, Emergency Response Professionals, Hospitals and other healthcare professional for the Intended Use purpose below:*

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## Discussion of Clinical Tests Performed:

*Not Applicable*

## Conclusions:

*Modern Healthcare Corp., Surgical Face Mask, type: Tie-on and Ear-loop, has the same intended use and technological characteristics as the predicated devices (K060776). Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new question of safety or effectiveness. Modern Healthcare Corp., Surgical Face Mask, type: Tie-on and Ear-loop, is substantially equivalent to the predicated device.*

*Thus the new device is substantially equivalent to the predicate devices.*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Modern Healthcare Corporation  
C/O Dr. Ke-Min Jen  
Official Correspondent  
ROC Chinese-European Industrial Research Society  
No. 58, Fu-Chiun Street  
Hsin-Chu City  
30067 TAIWAN, ROC

MAR 21 2007

Re: K063043

Trade/Device Name: Surgical Face Mask, Type: Tie-on, Ear Loop  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: II  
Product Code: FXX  
Dated: January 23, 2007  
Received: January 29, 2007

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Dr. Jen

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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## Indications for Use

510 (K) Number ( If Known ): K063043

Device Name: Surgical Face Mask, Type: Tie-on, Ear-loop

### Indications for Use:

The Surgical Face Mask of different colors (Green, White, Blue and Pink) is a device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluid and particulate material.



AUTION:

This Surgical Face Mask is non-sterilized and disposable for use.

Prescription Use \_\_\_\_\_

AND/OR

Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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